

K954552

9. SUMMARY OF SAFETY AND EFFECTIVENESS DATA

SUBMITTER: InterVentional Technologies Inc. (IVT)
DATE: September 28, 1995
DEVICE NAME: Guidewire
PROPRIETARY NAME: 0.014" Railwire™
CONTACT: Michael E. Klicpera, Esq.
Corporate Counsel
CLASSIFICATION: Guidewires classified under 21 CFR 870.1330

PREDICATED DEVICES:

IVT is claiming substantial equivalence to the following predicate medical devices:

1. IVT 0.014" Guidewire (K895903)
2. IVT 0.014" Peripheral Guidewire (K882804)
3. Cook Family of Guidewires

1. DEVICE DESCRIPTION:

The IVT 0.014" Railwire™ is constructed from a stainless steel core wire that is distally tapered and fitted with a gold alloy coil. To minimize blood vessel trauma and to facilitate maneuverability, the distal tip is extremely flexible.

The core is nominally 0.0136" in diameter. The coil, approximately 1.2" in length with a nominal diameter of 0.0136", is made from a single continuous radiopaque gold alloy wire that has two different wind spacings. Both the core and coil are single continuous pieces that are secured together at two points. The core is inserted into the coil lumen and attached at the distal end utilizing a plasma arc technology that brazes the end of the gold alloy coil to the cylindrical bulb.

This special process results in the formation of a gold alloy sphere. The proximal end of the coil is secured to the stainless steel core using a silver alloy solder. This design provides both unibody integrity and flexibility.

The IVT Railwire™ will be manufactured in various lengths ranging from 100 to 300 cms. All Railwire™s will receive a final parylene (poly-para-xylyene) coating prior to packaging and sterilization.

Steering or guidance of the wire is achieved by shaping the tip and rotating the proximal end of the wire, thereby transmitting torque along the axis of the core to the flexible tip. This redirects the shaped tip of the Railwire™ allowing selection or avoidance of branch vessels, thus facilitating navigation in tortuous vessels.

2. INTENDED USE:

The IVT 0.014" Railwire™ is intended to facilitate the navigation and placement of angioplasty and interventional devices through tortuous peripheral and coronary vessels.

3. SUBSTANTIAL EQUIVALENCE:

The intended use of the IVT 0.014" Railwire™ is the same as that for other predicate guidewire devices. The materials and design of the Railwire™ are similar to these previously FDA cleared guidewires. The technical characteristics of the Railwire™ do not introduce new questions regarding safety or effectiveness of cardiovascular guidewires. The labeling associated with the Railwire™ provides similar information as the predicate devices.

Biocompatibility and physical performance testing demonstrates the Railwire™ product to be safe and effective. Information provided in the 510(k) submission supports the determination of substantial equivalence.

In summary IVT has provided evidence that shows the Railwire™ device to be safe and effective. This guidewire is considered to be substantially equivalent to similar marketed devices.